REMARKS

Claims 20, 22, and 23 remain pending in this application, and new Claims 31-36 have been added. Claim 20 has been amended, and support for this amendment, as well as for the new claims, can be found throughout the specification, for example, in Example 4. No new matter has been added. Reconsideration of the application in view of these amendments and the following remarks is respectfully requested.

The pending claims stand rejected under 35 USC §112, first paragraph, as failing to meet the enablement requirement and as lacking written description. The Examiner states that the genetic engineering technique described in the specification is not sufficient to arrive at the claimed invention, and there is no convincing evidence that the specification allows one of skill in the art to produce, by the genetic engineering technique, a phage able to delay inactivation by an animal's host defense system.

Applicants maintain that the specification is enabling with respect to the claimed methods of producing a genetically engineered bacteriophage that, through the creation of a fusion protein expressed on the surface of the bacteriophage, can delay inactivation or clearance by a host innate immune system.

As explained in further detail in the Declaration of Dr. Carl Merril, one of the named inventors, being submitted herewith, the specification describes at Example 4, genetic engineering of phage to express molecules that antagonize the host innate immune system, thereby enabling the phage to delay inactivation or clearance by the immune system. It includes as an example the use of the orfx gene, which encodes a carboxy-terminal tail protein of lambda coliphage, one for which it is known that foreign nucleotide sequences can be introduced without there being disruption of the structure or function of the phage. Montag et al., J Bacteriol 171: 4378 (1989). The tail surface protein expressed by the orfx gene is made into a fusion protein with the host defense antagonizing peptide. Example 5 confirms that the genetically engineered phage delay inactivation by the host innate immune system, compared to wild-type phage and Example 6 confirms that the genetically engineered phage has a greater capacity than wild type phage to prevent lethal infections in mice. Applicants remind the Examiner that MPEP 608.01(p) allows prophetic (or paper) examples to describe a manner and process of making invention, which has not actually been conducted.

Further, the state of the art at the April 1994 time of filing the present application with regard to predictability of altering the phage surface to delay inactivation or clearance by an animal's innate immune system can be determined by several references previously submitted and of record in this application. Specifically, Lambris, J. D. et al, "Use of synthetic peptides in exploring and modifying complement reactivities" in Activators and Inhibitors of Complement, ed. R. Sim, Kluwer Academic Publishers, Boston, 1993, is a representative paper exemplifying the state of the art with regard to peptides that modify complement reactivities foreign to bacteriophages. Isaacs et al., Proc Natl Acad Sci USA 89: 628 (1992) shows that viruses that infect animals encode proteins that inhibit complement activation, thus inhibiting complement activation is compatible with the viability of a virus. Montag et al., J Bacteriol 171: 4378 (1989) is a representative paper exemplifying the state of the art with regard to the display of a foreign peptide on the surface of a phage while preserving infectivity. The conclusion to be drawn from these papers is that altering the phage surface to delay inactivation by an animal's innate immune system through specific genetic engineering techniques was enabled by the patent specification, and sufficiently described therein, in view of the state of the art at the April 1994 time of filing.

Several additional references being submitted herewith provide evidence that the method set forth in the pending claims, that is, genetically engineering a bacteriophage by fusing a gene for a surface protein with an oligonucleotide for a desired peptide to create a fusion protein, such that said fusion protein is expressed on the surface coat of the bacteriophage, is fully enabled by the disclosure set forth in the specification. Further, the references support the disclosure in the specification that through genetic engineering, the phage can be modified such that the fusion protein expressed on the surface coat of the phage is able to delay inactivation or clearance by the host innate immune system.

Thus, the genetic engineering technique described in the specification is sufficient to arrive at the claimed invention, and there is convincing evidence that the specification allows one of skill in the art to produce, by the genetic engineering technique as claimed, a phage able to delay inactivation or clearance by the host innate immune system. Withdrawal of the rejection for lack of enablement and written description is therefore respectfully requested.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

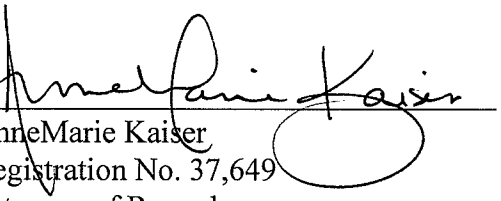
Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 16, 2008

By: 

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